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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,856	09/23/2003	Bradley Michael John Stringer	2240-1-001DIV1CON1	3163
23565	7590	09/23/2005	EXAMINER	
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			KETTER, JAMES S	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 09/23/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,856

Applicant(s)

STRINGER, BRADLEY MICHAEL
JOHN

Examiner

James S. Ketter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-65 is/are pending in the application.
- 4a) Of the above claim(s) 52, 53, 63 and 64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-51, 54-62 and 65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/836,440.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Applicant's election without traverse of Group I, claims 28-51, 54-62 and 65 in the reply filed on 1 July 2005 is acknowledged.

Claims 52, 53, 63 and 64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1 July 2005.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-44, 47-51, 54-62 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9 and 20 of U.S. Patent No. 6,340,592, as follows: instant claims 28-44, 47-51 and 54-57 over patented claim 20; instant claims 58, 59, 62 and 65 over patented claim 1; and instant claims 60 and 61 over patented claim 9. Although the conflicting claims are not identical, they are not patentably distinct from each other because an obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct

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from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). The MPEP states, at §804, that

[t]he specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

With respect to instant claims 28-44, 47-51, 54-57 and 61, the instant claim in each instance is more narrowly drawn than the patented claim. However, the portion of US Patent 6,340,592 that supports each of claims 28-44, 47-51, 54-57 and 61 defines the patented invention as including embodiments which possess each of the narrower limitations of the instant claims. With respect to instant claims 58-60 and 62, an obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are generic to all that is recited in the respective claims of the patent, i.e., the patented claims fall entirely within the scope of each of instant claims 58-60 and 62.

Claims 28-51, 54-62 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9 and 20 of U.S. Patent No. 6,197,585, as follows: instant claims 28-51 and 54-57 over patented claim 20; instant claims 58, 59, 62 and 65 over patented claim 1; and instant claims 60 and 61 over patented claim 9. Although the conflicting claims are not identical, they are not patentably distinct from each other because an obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). The MPEP states, at §804, that

[t]he specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

With respect to instant claims 28-44, 47-51, 54-57 and 61, the instant claim in each instance is more narrowly drawn than the patented claim. However, the portion of US Patent 6,197,585 that supports each of claims 28-44, 47-51, 54-57 and 61 defines the patented invention as including

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embodiments which possess each of the narrower limitations of the instant claims. With respect to instant claims 58-60 and 62, an obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are generic to all that is recited in the respective claims of the patent, i.e., the patented claims fall entirely within the scope of each of instant claims 58-60 and 62.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-33, 36-41, 45-48, 54-62 and 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to methods that include a step of immortalization of cells followed by termination of the immortalization. The specification describes the use of conditional oncogenes for this pair of process steps. However, no description is present for any other mechanism by which a cell might be immortalized followed by the deliberate reversal of the immortalization. Oncogenes would not constitute a representative sample of all such means, as the mechanism of immortalization would be very different from chemical or physical means. Furthermore, oncogenes are reversible by virtue of the ability to cease expression. A mutation

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produced by a mutagen or by radiation would not be reversible by this mechanism, or indeed by any mechanism short of back-mutation. Immortalization by a compound not by mutagenesis, but by a shift in gene expression, e.g., a transforming growth factor, similarly would not be reversed by the mere removal of the compound. It is not apparent that reversible immortalization means were known in the art other than oncogenes, and therefore the mere description of a function would not have led one of skill to the structure of a means possessing that function. As such, the claimed invention would not have been described in such a way as to convey to one of skill in the art that Applicant was in possession of the full scope of the invention as claimed.

Claims 28-33, 36-41, 45-48, 54-62 and 65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immortalizing agents which are oncogenes, does not reasonably provide enablement for other immortalizing agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The following factors have been considered in the rejection:

The amount of direction or guidance presented in the specification, the presence or absence of working examples. The specification does not describe immortalization means other than oncogenes, which are reversible as disclosed.

The nature of the invention, and the state of the prior art. The means by which the cell is immortalized must be deliberately reversible. Immortalization by mutation is by chance, and is reversible only by another chance event, i.e., a fortuitous back mutation. Immortalization by transforming factors generally does not reverse once the compound is withdrawn, as the cells have shifted states into an immortalized or transformed state.

The predictability or unpredictability of the art. As transformation or immortalization by mutation is a chance event, it is inherently a trial-and-error process, and thus unpredictable for any given cell or sample of cells. Therefore, reversal of the process by trial-and-error is equally, or even more so, unpredictable. If the entire sample of cells cannot have the immortalization reversed reliably, then the method will not be useable.

Conclusion. Were the skilled practitioner to have endeavored to practice the claimed invention for other than oncogenes as the immortalizing agent, said practitioner first would have turned to the specification for guidance. However, as set forth above, the specification fails to set forth workable alternatives to conditional oncogenes. Next, said practitioner would have turned to the prior art for guidance in selecting an immortalizing agent. However, as set forth above, the other methods of immortalizing cells are not known to be easily or reliably reversible. Finally, the practitioner would have been forced to employ empirical experimentation to find other methods of reversibly immortalizing cells. However, neither the specification nor the art sets forth any alternatives to oncogenes for this purpose, and thus do not teach assays or routine methods for obtaining other such reversible immortalization means. Experimentation to find a means or structure which performs a desired function, where no examples or theory is available either from the specification or the prior art, would have been deemed undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 49-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 49 and 50, and therefore 51 which depends from 50, recite "the immortalising oncogene". However, there is insufficient antecedent basis for this language in claim 47.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jsk
September 14, 2005



JAMES KETTER
PRIMARY EXAMINER